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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference 2002OPA2714	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR2003/000544**	International filing date *(day/month/year)* **20 MARCH 2003 (20.03.2003)**	Priority date *(day/month/year)* 16 JULY 2002 (16.07.2002)

International Patent Classification (IPC) or national classification and IPC

IPC7 C07K 16/18

Applicant

EYEGENE INC. et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [X] Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
16 FEBRUARY 2004 (16.02.2004)	11 NOVEMBER 2004 (11.11.2004)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer LEE, Yoon Won Telephone No. 82-42-481-5852

Form PCT/IPEA/409 (cover sheet) (July 1998)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR2003/000544

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-11 13 , as originally filed
pages _____ , filed with the demand
pages _____, filed with the letter of _____

☒ the claims:
pages _____ , as originally filed
pages _____ , as amended (together with any statment) under Article 19
pages _____ , filed with the demand
pages 12 , filed with the letter of 04/11/2004

☒ the drawings:
pages 1/5-5/5 , as originally filed
pages _____ , filed with the demand
pages _____, filed with the letter of _____

☒ the sequence listing part of the description:
pages 1-5 , as originally filed
pages _____ , filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☒ the language of publication of the international application(under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained inthe international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form

☒ The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☒ the claims, Nos. 3-5, 7

☐ the drawings, sheets _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 6, 8-10

because:

☒ the said international application, or the said claims Nos. 6, 8-10 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject-matter of claims 6, 8-10 does not require an international preliminary examination with respect to industrial applicability as it is directed to a diagnostic method practiced on the human or animal body (Article 34(4)(a)(i), Rule 67.1(iv)).

☐ thedescription, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-2	NO
Inventive step (IS)	Claims		YES
	Claims	1-2	NO
Industrial applicability (IA)	Claims	1-2	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: Stolwijk, T. R. et al. "Analysis of tear fluid proteins in insulin-dependent diabetes mellitus" In:Acta Ophthalmologica, 1994, Vol.72(3), pp.357-362

D2:Peebles, R. S. Jr. et al. "IgA, IgG and IgM quantification in bronchoalveolar lavage fluids from allergic rhinitics, allergic asthmatics, and normal subjects by monoclonal antibody-based immunoenzymetric assays" In:J. Immunol. Methods, 1995, Vol.179, pp.77-86

1. Novelty and Inventive Step

The present invention relates to the use of IgA polypeptide for diagnosing diabetic retinopathy among diabetic mellitus(DM) patients. The subject matter of the present invention is that the value of IgA in diabetic retinopaty patients is lower than that of IgA in DM patients without retinopathy.

D1 is considered to represent the closest prior art and discloses a statistical analysis of the protein composition in tear fluids from DM patients without retinopathy, DM patients with proliferative retinopathy and healthy controls. Secretory immunoglobulin A (sIgA), lactoferrin, lysozyme and tear specific pre-albumin are analyzed using HPLC and SDS-PAGE. The result teaches that in patients without retinopathy the sIgA concentration is increased compared with that of healthy controls; the level of sIgA is decreased below the level of healthy control. D2 discloses the role of sIgA in various atopic diseases.

The subject matters of the present invention and D1 are the same in that diabetic retinopathy is related to the decreased level of IgA. The person skilled in the art would easily suggest the use of IgA for diagnosing diabetic retinopathy from D1. Thus, the present invention does not satisfy the criteria set forth in Article 33(2) and (3) PCT because the subject matter of claims 1, 2 is not novel in respect of the prior art as defined in the regulations (Rule 64(1)-(3) PCT) and/or does not involve an inventive step (Rule 65(1)(2) PCT).

2. Industrial Applicability

Claims 1-2 are considered to be industrially applicable under PCT Article 33(4).

[What is Claimed is]

1. An Immunoglobulin A protein and an analogous protein or a protein fragment thereof described in SEQ ID NO:1 wherein the protein is effective for diagnosing diabetic retionpathy.

2. The protein fragment according to claim 1, wherein the protein fragment comprises a peptide sequence described in SEQ ID NO:2.

3. An antibody specifically binding the protein of claim 1 or 2.

4. A kit for diagnosing diabetic retinopathy comprising the antibody of claim 3.

5. The kit according to claim 4, further comprising enzyme peroxidase, alkaline phosphatase or biotin conjugated-anti-Immunoglobulin A antiboody.

6. A method for diagnosing diabetic retinopathy, comprising:

a) treating the antibody of claim 2 with a blood sample and an peroxidase, alkaline phosphatase or biotin conjugated-anti-Immunoglobulin A protein; and

b) measuring optical density of the compound,

wherein diabetic retinopathy is diagnosed when the measured value represents optical density (ELISA value) lower than normal one.

7. An Immunoglobulin A gene and an analogous gene of SEQ ID NO:3 for coding the protein of claim 1 or 2.